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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,115	08/06/2007	**Malcolm Brown**	39262/330604	3900

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DIANA HOUSTON
SMITH & NEPHEW, INC.
1450 BROOKS ROAD
MEMPHIS, TN 38116

EXAMINER	
PEPITONE, MICHAEL F	
ART UNIT	**PAPER NUMBER**
1796	
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03/30/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/584,115	BROWN, MALCOLM	
	Examiner	Art Unit	
	MICHAEL PEPITONE	1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 June 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :11/9/06, 5/21/07, 6/4/07, 3/13/08, 4/9/08, 7/15/08, 8/13/08, 1/28/09, 2/13/09, 5/4/09, 8/7/09, 10/27/09 .

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22-23 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22 recites the limitation "said growth" in line 2. It is unclear which growth it is referring to in claim 19. For the purpose of examination, bone growth agent was used.

Claim 23 recites the limitation "said agent" in line 2. It is unclear which agent it is referring to in claim 19. For the purpose of examination, chemotherapeutic agent was used.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7-8, 18, and 28-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Brocchini *et al.* (US 2002/0082362).

Regarding claims 1-2, 7-8: Brocchini *et al.* teaches a biodegradable polyacetal polymer (abstract; ¶ 3, 16-20), wherein of polymer of Formula (I) is prepared by reacting a diol of

Formula (II) with a divinyl ether of Formula (III) (¶ 82-86); wherein the diol of Formula (II) is a polyethylene glycol or polypropylene glycol having a molecular weight in the range of 100-20,000, most preferably 200-5,000, in particular a polyethylene glycol having a molecular weight of approximately 200-4,000 (¶ 91). Brocchini *et al.* teaches a specific embodiment (ex. 1; polyacetal 3) comprising the reaction of poly(ethylene glycol) {mw = 3,400 g/mol} with tri(ethylene glycol) divinyl ether in the presence of *p*-toluenesulfonic acid (¶ 151-153) [see ex. 7 as well (¶ 169-178)].

Regarding claim 3: Brocchini *et al.* teaches a specific embodiment (ex. 5; ¶ 161-166) comprising the reaction of poly(ethylene glycol) {mw = 3,400 g/mol} with an amino functionalized bis-vinyl ether monomer {containing a diamide bond (diamino acid ester)} (compound 11; ¶ 161-164) in the presence of *p*-toluenesulfonic acid (¶ 165-166).

Regarding claim 4-5, 18, 28-31: Brocchini *et al.* teaches a specific embodiment (ex. 6; ¶ 167-168) comprising the reaction of poly(ethylene glycol) {mw = 3,400 g/mol} with an achiral bis-vinyl ether monomer having a conjugate bioactive compound (compound 16; ¶ 96-106, 167) in the presence of *p*-toluenesulfonic acid (¶ 165-166) {the as synthesized polymer-drug conjugate is a medical device}.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 6, 14, 17, 19-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brocchini *et al.* (US 2002/0082362) as applied to claim 1 above.

Regarding claims 6, 14, 17 and 19-26: Brocchini *et al.* teaches the basic claimed composition [as set forth above with respect to claim 1], wherein the polymer-drug conjugate of the invention (¶ 109, 112, 167-168) can be combined with preserving agents (¶ 110), pharmaceutically acceptable liquid carriers (¶ 112) and excipients (¶ 115).

Brocchini *et al.* does not teach a specific embodiment comprising the polymer-drug conjugate of the invention (¶ 112, 167-168) combined with preserving agents, pharmaceutically acceptable liquid carriers, such as aqueous dextrose and glycols, or excipients such as polysaccharides {starch} and sodium chloride. However, at the time of invention a person of ordinary skill in the art would have found it obvious to have prepared the polymer-drug conjugate with preserving agents, pharmaceutically acceptable liquid carriers, such as aqueous dextrose and glycols, or excipients such as polysaccharides {starch} and sodium chloride based on the invention of Brocchini *et al.*, and would have been motivated to do so since Brocchini *et al.* suggests that intravenous injectable composition can be prepared using preserving agents, pharmaceutically acceptable liquid carriers, such as aqueous dextrose and glycols (¶ 110, 112); and lyophilized or freeze dried compositions can be prepared using excipients such as polysaccharides {starch} and sodium chloride (¶ 115). {note: claims 20-24 further defines species of: growth factors {claim 20}, antibiotics {claim 21}, bone growth factors {claim 22}, chemotherapeutic agents {claim 23}, and pain killers {claim 24} recited in the Markush list of claim 19. However, as claimed, such species only further define the genus of optional materials and are not required}.

Claims 9-10, 12-13, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brocchini *et al.* (US 2002/0082362) as applied to claim 1 above, in further view of Neuenschwander *et al.* (US 5,665,831).

Regarding claims 9-10, 12-13, and 16: Brocchini *et al.* teaches the basic claimed composition [as set forth above with respect to claim 1], wherein the diol may also comprise any diol suitable for use in biomaterials (¶ 91).

Brocchini *et al.* does not a specific diol comprising polyesters. However, Neuenschwander *et al.* teaches biocompatible block copolymers (abstract) comprising macrodiols based on α,ω-dihydroxypolyethers and α,ω-dihydroxypolyesters (2:9-20), wherein the macrodiols based on α,ω-dihydroxypolyesters are obtained by ring opening polymerization of lactones {dilactide, diglycolide, ε-caprolactone}, and lactams (2:26-41; see examples). Neuenschwander *et al.* teaches the molecular weight of the macrodiol of about 300 to 10,000 daltons (2:43-54), and the resulting copolymer can contain a conjugate antibiotic (9:25-31). Brocchini *et al.* and Neuenschwander *et al.* are analogous art because they are concerned with a similar technical difficulty, namely the preparation of biocompatible block copolymers containing conjugate bioactive compounds prepared from (macro)diols. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined α,ω-dihydroxypolyesters obtained by ring opening polymerization of lactones {dilactide, diglycolide, ε-caprolactone}, and lactams (2:26-41) having molecular weights of about 300 to 10,000 daltons, as taught by Neuenschwander *et al.* in the invention of Brocchini *et al.*, and would have been

motivated to do so since Neuenschwander *et al.* suggests that α,ω-dihydroxypolyethers and α,ω-dihydroxypolyesters are equivalent macrodiols (2:9-20) [see MPEP 2144.06].

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brocchini *et al.* (US 2002/0082362) as applied to claim 1 above, in further view of Shalaby (US 6,503,991).

Regarding claim 11: Brocchini *et al.* teaches the basic claimed composition [as set forth above with respect to claim 1], wherein the diol may also comprise any diol suitable for use in biomaterials (¶ 91).

Brocchini *et al.* does not a specific diol comprising a carbonate. However, Shalaby teaches biocompatible block copolymers (abstract) comprising a pre-polymer prepared from an alkanediol containing a carbonate linkage (1:61-2:3). Brocchini *et al.* and Shalaby are analogous art because they are concerned with a similar technical difficulty, namely the preparation of biocompatible block copolymers prepared from diols. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined a pre-polymer prepared from an alkanediol containing a carbonate linkage, as taught by Shalaby in the invention of Brocchini *et al.*, and would have been motivated to do so since Shalaby suggests that carbonate linkages provide biomedical articles having controlled absorption and reduced hydrolytic instability (2:34-42).

Claims 15 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brocchini *et al.* (US 2002/0082362) as applied to claims 14 and 25 above, in further view of Wise *et al.* (US 6,071,982).

Regarding claim 15: Brocchini *et al.* teaches the basic claimed composition [as set forth above with respect to claims 14 and 25], wherein the polymer-drug conjugate of the invention may also include buffers (¶ 112).

Brocchini *et al.* does not a specific buffer. However, Wise *et al.* teaches bioerodible polymers (abstract) comprising buffers such as calcium phosphate (5:21-59) and calcium phosphate fibers (6:58-59). Brocchini *et al.* and Wise *et al.* are analogous art because they are concerned with a similar technical difficulty, namely the preparation of biodegradable polymers comprising buffers. At the time of invention a person of ordinary skill in the art would have found it obvious to have combined calcium carbonate and/or calcium phosphate fibers as a buffer, as taught by Wise *et al.* in the invention of Brocchini *et al.*, and would have been motivated to do so since Wise *et al.* suggests that calcium carbonate and calcium phosphate counteracts the effects of irritation, inflammation, and swelling caused by acidic products generated upon hydrolysis within the body (5:21-39).

The prior art made of record and not relied upon is considered pertinent to applicants' disclosure. See attached form PTO-892.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL PEPITONE whose telephone number is (571)270-3299. The examiner can normally be reached on M-F, 7:30-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Eashoo can be reached on 571-272-1197. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mark Eashoo/
Supervisory Patent Examiner, Art Unit 1796

MFP
26-March-10